



"ROCKS, Martin"  
<Martin.Rocks@health.  
gov.au>  
02/06/2015 08:19

To MinCorro <MinCorro@health.gov.au>,  
cc  
bcc  
Subject FW: Referral: Emailing: TGA Regulatory Reform  
[SEC=UNCLASSIFIED]

1 attachment



SPRN21015052813440.pdf

UNCLASSIFIED

RECEIVED

- 2 JUN 2015

TGA  
FW

Division:

Minister:

Milestone:

10  15  20

INFO  
 VIP  
 PM

**From:** ROCKS, Martin **On Behalf Of** Minister Nash

**Sent:** Tuesday, 2 June 2015 8:20 AM

**To:** Health Referrals

**Cc:** WOOD, Emma

**Subject:** FW: Referral: Emailing: TGA Regulatory Reform [SEC=UNCLASSIFIED]

sep williams / ADIA

Please arrange M response to Williams noting Minister Nash has written to Mr Williams directly and copy of response will be enclosed.

**From:** LEE, Annie **On Behalf Of** Minister Ley DLO

**Sent:** Tuesday, 2 June 2015 7:43 AM

**To:** Minister Nash

**Subject:** Referral: Emailing: TGA Regulatory Reform [SEC=UNCLASSIFIED]

link to MCIS-00792  
MCIS-01086  
MCIS-01000  
MCIS-01001

Annie Lee | Junior Departmental Liaison Officer  
Office of the Hon Sussan Ley MP  
Minister for Health  
Minister for Sport  
Parliament House Suite M1- 41 Canberra ACT 2600  
Phone (02) 6277 7220 | Email: [annie.lee@health.gov.au](mailto:annie.lee@health.gov.au)

**From:** WYLDECK, Adam  
**Sent:** Monday, 1 June 2015 9:04 PM  
**To:** Minister Ley DLO  
**Cc:** WOOD, Emma  
**Subject:** FW: Emailing: TGA Regulatory Reform [SEC=UNCLASSIFIED]

Hi Guys, I think this is one for Nash's office. Will you refer to Martin Rocks?

**From:** Ley, Sussan (MP) [mailto:[Sussan.Ley.MP@aph.gov.au](mailto:Sussan.Ley.MP@aph.gov.au)]  
**Sent:** Monday, 1 June 2015 8:52 PM  
**To:** Minister Ley; WYLDECK, Adam  
**Subject:** FW: Emailing: TGA Regulatory Reform [SEC=No Protective Marking]

**From:** Williams, John (Senator)  
**Sent:** Thursday, 28 May 2015 1:01 PM  
**To:** Ley, Sussan (MP)  
**Subject:** Emailing: TGA Regulatory Reform

Hello Sussan,

Received this letter in our Mail today from Troy Williams CEO of Australian Dental Industry Association

Drawing attention to the degree of urgency re the changes that are expected to be approved by the Federal Executive Council TODAY 28<sup>th</sup> May.

Your comments on this would be appreciated.

Kind Regards



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Ref: 11.11.14K — 26 May 2015

Senator the Hon. John R. Williams  
Senator for New South Wales  
144 Byron Street  
INVERELL NSW 2360



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Dear Senator

**RE: TGA Regulatory Reform – Low value turnover scheme abolition**

As the peak business organisation representing manufacturers and suppliers of dental products, the Australian Dental Industry Association (ADIA) seeks your assistance in securing an urgent review of proposed reforms to the charges levied by the Therapeutic Goods Administration (TGA). Under the guise of red-tape reduction, the net impact is to increase by around thirty percent the charges paid by the dental industry to the TGA.

The TGA is the nation's regulator for medicines and medical devices which operates on a cost-recovery basis. A considerable portion of the TGA's revenue is derived by businesses that pay to place entries on the Australian Register of Therapeutic Goods (ARTG), a listing of medical devices that can be lawfully supplied in Australia.

Currently, the regulation allows a business to claim an exemption from certain TGA charges if the sale of products produces revenue that is fifteen times (or less) the TGA charge. The proposed reform eliminates the exemption the moment the product is sold. There are some associated reductions in business red-tape as a result of revised TGA's documentary requirements; however, any savings to businesses in the dental industry are entirely negated by higher TGA charges.

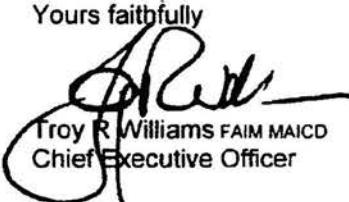
**There is a degree of urgency as the changes are expected to be approved by the Federal Executive Council on Thursday, 28 May 2015, and commence on Wednesday, 1 July 2015.**

Of significant concern is that the Regulatory Impact Statement (RIS) prepared by the TGA in support of the proposal omitted any reference to the higher fees that the dental industry will face. It was on the basis of the flawed RIS that the Assistant Minister for Health is understood to have accepted the need for reform.

The outcome of the regulatory reform spells bad news for jobs in the industry as the viability of businesses that sell dental products will come into question. Patient treatment options will also be limited as the higher TGA fees are likely to result in some products being withdrawn from the market.

Any assistance that you are able to provide in terms of drawing attention to this matter with a view to securing a proper analysis of the proposed reform is appreciated.

Yours faithfully

  
Troy R. Williams FAIM MAICD  
Chief Executive Officer

*Any assistance that you are  
able to provide is appreciated!*



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